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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,624	10/13/2005	Jesper Mortensen Haaning	0267us310	4465
69987 7590 04/17/2009 BAYER HEALTHCARE LLC Law & Patents 800 Dwight Way BERKELEY, CA 94710				
EXAMINER				
ROBINSON, HOPE A				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
04/17/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,624

Applicant(s)

HAANING ET AL.

Examiner

HOPE A. ROBINSON

Art Unit

1652

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 7, 13, 14, 25-28, 30, 32, 35, 50, 51, 53-55, 62 and 63 is/are pending in the application.
- 4a) Of the above claim(s) 51, 53, 54, 62 and 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7, 13, 14, 25-28, 30, 32, 35, 50 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

1. Applicant's election without traverse of Group I (claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 47, 50 and 55, species L65Q) on March 26, 2008 is acknowledged.

Claim Disposition

2. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50-51, 53-55 and 62-63 are pending. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are under examination. Claims 51, 53-54 and 62-63 are withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Maintained-Basis For NonStatutory Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In*

re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b). 1-50 and 55-56

4. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-20, 25, 31-43, 45-48 of copending Application No. 11/021,239. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending application claim is directed to a recombinant FVII or FVIIa polypeptide variant having clotting activity comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO:1 in no more than 15 amino acid residues, wherein the arginine residue in position 36 of SEQ ID NO:1 is substituted with a negatively charged amino acid residue in the variant, and wherein amino acid positions of the variant are numbered according to SEQ ID NO:1.

The two sets of claims differ as the instant claims recite "modifications selected from L39, I42, S43, K62, L65, F71, E82 and F275", however the copending application claim contemplate a modification at position 36. The two sets of claims are related as a genus and species since the copending claims would be the genus of the specific species recited in the instant application with the open language of comprising no more than 15 amino acid substitutions, thus the recited position would be encompassed and is obvious in view of the disclosure that positions 46-406 of SEQ ID NO:1 can be mutated (see paragraph 0145 of the instant application specification).

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of

ordinary skill in the art would be motivated to modify the copending claims to recite, for example the species that is contained in the instant application because the copending application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the copending claims are a genus over the copending species. Thus, the copending claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

5. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 16-19, 26, 29-33 and 41-48 of copending Application No. 11/381, 713. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L)

in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a FVII or FVIIa polypeptide variant having an amino acid sequence comprising 3-15 amino acid modifications relative to human Factor VII (hFVII) or human Factor VIIa (hFVIIa) having the amino acid sequence shown in SEQ ID NO:2, wherein said amino acid sequence of the variant comprises an amino acid substitution in position 10 and 32 and wherein a sugar moiety is covalently attached to an introduced in vivo N-glycosylation site located outside the Gla domain.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues" however the copending application claims have the open language of comprising thus the recited 3-15 amino acid substitutions can be 1-15 amino acid substitutions. Moreover, the recited sugar moiety in the copending application is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10 and 32", however, note that the depending claims in the instant application recite the same positions in dependent claim 14, for example. Furthermore, the structure of SEQ ID NO:1 in the instant application and SEQ ID NO:2 of the copending application, are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant

application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

6. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 16-19, 26, 29-33, 41-43 and 48 of copending Application No. 11/381, 717. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). *See In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to

a Factor VII (FVII) or Factor VIIa (FVIIa) polypeptide variant having an amino acid sequence comprising 3-15 amino acid modifications relative to human Factor VII (hFVII) or human Factor VIIa (hFVIIa) having the amino acid sequence shown in SEQ ID NO:2, wherein said amino acid sequence of the variant comprises an amino acid substitution in position 10 and 32 and wherein a sugar moiety is covalently attached to an introduced in vivo N-glycosylation site located outside the Gla domain.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues" however the copending application claims have the open language of comprising thus the recited 3-15 amino acid substitutions can be 1-15 amino acid substitutions. Moreover, the recited sugar moiety in the copending application is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10 and 32", however, note that the depending claims in the instant application recite the same positions in dependent claim 14, for example. Furthermore, the structure of SEQ ID NO:1 in the instant application and SEQ ID NO:2 of the copending application, are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious

variation of the instant application claim, therefore *prima facie* obvious.

7. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 16-19, 26, 29-33, 41-43 and 48 of copending Application No. 11/381, 718. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a FVII or FVIIa polypeptide variant having an amino acid sequence comprising 3-15 amino acid modifications relative to human Factor VII (hFVII) or human Factor VIIa (hFVIIa) having the amino acid sequence shown in SEQ ID NO:2, wherein said amino

acid sequence of the variant comprises an amino acid substitution in position 10 and 32 and wherein a sugar moiety is covalently attached to an introduced *in vivo* N-glycosylation site located outside the GlA domain.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues" however the copending application claims have the open language of comprising thus the recited 3-15 amino acid substitutions can be 1-15 amino acid substitutions. Moreover, the recited sugar moiety in the copending application is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10 and 32", however, note that the depending claims in the instant application recite the same positions in dependent claim 14, for example. Furthermore, the structure of SEQ ID NO:1 in the instant application and SEQ ID NO:2 of the copending application, are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

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8. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 16-19, 26, 29-33, 41-43 and 48 of copending Application No. 11/381, 705. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a Factor VII (FVII) or Factor VIIa (FVIIa) polypeptide variant having an amino acid sequence comprising 3-15 amino acid modifications relative to human Factor VII (hFVII) or human Factor VIIa (hFVIIa) having the amino acid sequence shown in SEQ ID NO:2, wherein said amino acid sequence of the variant comprises an

amino acid substitution in position 10 and 32 and wherein a sugar moiety is covalently attached to an introduced in vivo N-glycosylation site located outside the Gla domain.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues" however the copending application claims have the open language of comprising thus the recited 3-15 amino acid substitutions can be 1-15 amino acid substitutions. Moreover, the recited sugar moiety in the copending application is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10 and 32", however, note that the depending claims in the instant application recite the same positions in dependent claim 14, for example. Furthermore, the structure of SEQ ID NO:1 in the instant application and SEQ ID NO:2 of the copending application, are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

9. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being

unpatentable over claims 1, 20, 25, 31-41 and 57-64 of copending Application No. 11/379, 664. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a recombinant Factor VII (FVII) or Factor VIIa (FVIIa) polypeptide variant comprising the amino acid sequence shown in SEQ ID NO: 1 with six amino acid substitutions, said six amino acid substitutions consisting of a glutamic acid residue substituted for the arginine residue in position 36, a glutamine residue substituted for the proline residue in position 10, a glutamic acid residue substituted for the lysine residue in position 32, a glutamic acid residue substituted for the alanine residue in position 34, an asparagine residue substituted for the threonine residue in position 106, and an asparagine residue

substituted for the valine residue in position 253 of SEQ ID NO:1.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues " however the copending application claims have the open language of comprising thus the recited 6 amino acid substitutions can be 1-15 amino acid substitutions. Moreover, the recited sugar moiety in the copending application claim 31 is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10, 34, 106, 253 and 32", however, note that the depending claims in the instant application recites the same positions, see for example claim 14. Furthermore, the structure of SEQ ID NO:1 and SEQ ID NO:2 are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

10. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 41, 48, 64-67, 82-83, 91 and 95-96 of copending

Application No. 10/512,754. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a recombinant FVII or FVIIa polypeptide variant comprising the amino acid sequence shown in SEQ ID NO:2 with four amino acid substitutions consisting of P10Q, K32E, T106N, and V253N, wherein amino acid positions of the variant are numbered according to SEQ ID NO:2.

The two sets of claims differ as the instant claims recite "no more than 15 amino acid residues" however the copending application claims have the open language of comprising thus the recited 1-15 amino acid substitutions can be 20, 50, 100 or more amino acid substitutions. Moreover, the recited sugar moiety in the copending

application claim 31 is recited in dependent claim 27 of the instant application. In addition, the claims differ since the copending application recites "positions 10, 34, 106, 253 and 32", however, note that the dependent claims in the instant application recites the same positions, see for example claim 14. Furthermore, the structure of SEQ ID NO:1 and SEQ ID NO:2 are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

11. Claims 1-2, 7, 13-14, 25-28, 30, 32, 35, 50 and 55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-17, 54, and 59 of copending Application No. 10/549, 506. An obvious-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993);

and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other.

The instant claims are directed to a FVII or FVIIa polypeptide variant comprising an amino acid sequence which differs from the amino acid sequence of hFVII or hFVIIa shown in SEQ ID NO: 1 in no more than 15 amino acid residues, wherein the leucine (L) in position 65 of SEQ ID NO:1 is substituted with a glutamine (Q) in said variant sequence, and wherein amino acid positions of the variant sequence are Numbered according to SEQ ID NO:1. The copending claims are directed to a variant of FVII or FVIIa, wherein said variant comprises 1-15 amino acid modifications as compared to hFVIIa or FVIIa (SEQ ID NO:2), including at least one amino acid modification in a position selected from the group consisting of positions 196, 237 and 341.

The two sets of claims differ as the instant claims recites in some of the mutated positions, however, the instant claims would be a genus over the species recited in the copending application since the language is open with no more than 15 modifications. Furthermore, the instant disclosure contemplates the modifications in the copending application. Further, the structure of SEQ ID NO:1 and SEQ ID NO:2 are identical.

Although the scope of the claims herein differs, the two sets of claims are directed to similar inventions as the claim language has the similar material. One of ordinary skill in the art would be motivated to modify the instant claims to recite, for example the species that is contained in the copending application because the instant application claims recite the limitations in dependent claims and said embodiments

would clarify the claim by providing the specific species. Therefore, the instant claims are a genus over the copending species. Thus, the patented claims are an obvious variation of the instant application claim, therefore *prima facie* obvious.

Response to Arguments

12. Applicant's comments have been considered in full. Note that the rejections/objections of record have been withdrawn, except for the obvious-type double patenting rejections. Thus applicant's comments will not be addressed herein as it is moot. Applicant stated that the obvious-type double patenting rejections are to be held in abeyance. As no terminal disclaimers were filed, the rejections remain for the reasons set forth above.

Conclusion

13. No claims are presently allowable. The mutation L65Q is free of the art.

14. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HOPE A. ROBINSON whose telephone number is (571)272-0957. The examiner can normally be reached on Monday-Friday 9:00-6:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed, Ph.D., can be reached at (571) 272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Hope A. Robinson/

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